

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| APPLICANT(S) : | Mueller-Walz, et al. | CONFIRMATION. NO.: | 7066 |
| SERIAL NUMBER : | 10/574,302 | EXAMINER : | Kennedy, Nicoletta |
| FILING DATE : | November 2, 2006 | ART UNIT : | 1611 |
| FOR : | AEROSOL FORMULATIONS COMPRISING FORMOTEROL IN SUSPENSION | | |

Via EFS

DECLARATION UNDER 37 C.F.R. § 1.132

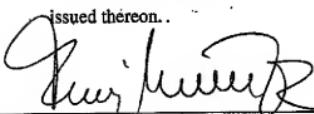
I, Rudi Mueller-Walz, Ph.D., declare:

1. I am currently Head of Early Development at SkyePharma, A.G. In this position I am responsible for development of oral controlled release formulations, inhaled dosage forms and device development. As evidenced by my *curriculum vitae*, already of record in this case, I have over twenty years of experience in the pharmaceutical industry, with emphasis on the development of products for pulmonary application.
2. I understand that in a telephonic interview on August 17, 2010 with my representatives David Johnson and Muriel Liberto, the Examiner requested more data regarding the crystalline structure of formoterol fumarate having a water content of 4.6% and 4.8%. In response to this request, further experiments were conducted and the results are summarized in Table 1.1 below.
3. The results summarized in the table show that the crystalline structure of formoterol fumarate having a water content of 4.6% is predominantly the dihydrate form. Likewise, the results show that the dihydrate form also predominates for formoterol fumarate having a water content of 4.8%. The water content was determined based on the Karl-Fischer ("KF") method. X-ray powder diffraction (XRPD) was used to determine the crystalline structure.

Table 1.1: XRPD analysis of Formoterol Fumarate having water content of 4.6% and 4.8%.

| Sample | Batch No. | Moisture Exposition | Water Content | Form |
|--------|-----------|---------------------|---------------|-----------|
| #9 | KN10031 | Yes | 4.8% | Dihydrate |
| #35 | KN10031 | No | 4.6% | Dihydrate |

4. As a person signing below, I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Title 18, United States Code, § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



Declarant's Signature

Full Name of Declarant: Rudi Mueller-Walz, Ph.D.

11 - Nov - 2010

Date